IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

FERRING B.V.,	:	
Plaintiff and Counterclaim-Defendant,	:	CIVIL ACTION
v.	:	No. 13-5909
MYLAN PHARMACEUTICALS INC.,	:	
Defendant and Counterclaim-Plaintiff.	:	

MEMORANDUM

ROBERT F. KELLY, Sr. J. **NOVEMBER 25, 2014**

Presently pending before the Court are the claim construction briefs by Plaintiff and Counterclaim-Defendant Ferring B.V. ("Ferring") and Defendant and Counterclaim-Plaintiff Mylan Pharmaceuticals Inc.'s ("Mylan"). There is one disputed claim term found in the patents-in-suit at issue. Having taken into consideration the parties' submissions and their arguments made during the Markman[1] hearing on November 17, 2014, the Court construes the disputed claim term as set out below.

I. BACKGROUND

This is an action for infringement of U.S. Patent No. 7,947,739 ("Patent '739"), U.S. Patent No. 8,022,106 ("Patent '106"), U.S. Patent No. 8,273,795 ("Patent '795") and U.S. Patent No. 8,487,005 ("Patent '005") (collectively, "the patents-in-suit").[2] Compl. ¶ 5. The patents-in-

[1] Markman v. Westview Instruments, Inc., 52 F.3d 967 (Fed. Cir. 1995).

[2] Subject matter jurisdiction is based upon 28 U.S.C. §§ 1331, 1338(a). Compl. ¶ 6. Venue is proper under 28 U.S.C. § 1391(c) and (d), as well as § 1400(b).

suit disclose and claim, *inter alia*, tranexamic acid formulations and methods of treating menorrhagia using such formulations. Id. ¶¶ 11-14. The claims of the patents-in-suit include one embodiment named Ferring's Lysteda®, a 650 mg tranexamic acid tablet formulation approved by the U.S. Food and Drug Administration ("FDA") for the treatment of heavy menstrual bleeding. Id. ¶¶ 15-16. This infringement action arose from the filing of Abbreviated New Drug Application ("ANDA") No. 20-5133 by Mylan, Mylan Inc. and Mylan Institutional seeking FDA approval to market generic tranexamic acid tablets containing 650 mg of tranexamic acid intended to be generic versions of Lysteda® before the patents-in-suit expire.[3] Id. ¶¶ 17-27.

On October 7, 2013, Ferring filed this action against Mylan, Mylan Inc. and Mylan Institutional.[4] Counterclaims alleging non-infringement and invalidity have been filed against Ferring. On August 21, 2014, Mylan's Motion to Transfer the Action to the United States District Court for the Northern District of West Virginia Pursuant to 28 U.S.C. § 1404(a) was denied.

On September 15, 2014, the parties filed a Joint Claim Construction Brief. On September 29, 2014, the parties each submitted an Opening Claim Construction Brief, addressing the construction of disputed terms, and, on October 30, 2014, an Answering Claim Construction Brief, addressing the construction of the disputed terms in each other's patents. Through the

[3]The filing of this Hatch-Waxman ANDA lawsuit triggered a 30-month stay, during which time the FDA is precluded from issuing a final approval of Mylan Pharma's ANDA. (Ferring's Opp'n Mylan's Mot. to Transfer at 2 n.1) (citing 21 U.S.C. § 355(c)(3)(C)). "To protect the patent holders from potentially infringing generics who are seeking approval, the Hatch-Waxman Act provided a means by which the patent holder could sue to prevent the marketing of the generic drug prior to its distribution." Paddock Labs., Inc. v. Ethypharm S.A., No. 09-3779, 2011 WL 149860, at *2 (D.N.J. Jan. 18, 2011); see also 21 U.S.C. § 355.

[4]On May 27, 2014, Mylan Inc. and Mylan Institutional were dismissed without prejudice from the case pursuant to a stipulation of the parties. (See Stip. & Order Dismissing Without Prejudice Defendants Mylan Inc. and Mylan Institutional ("Stipulation").) The Stipulation states that all three entities will be bound by any judgment and agree to provide discovery. (Id. ¶¶ 1, 3.)

meet-and-confer and briefing process, the parties narrowed the number of terms in dispute to only one term - "modified release material." On November 17, 2014, a Markman hearing was held. The Court now construes the disputed claim.

II. STANDARDS FOR CLAIM CONSTRUCTION

In order to prevail in a patent infringement action, a plaintiff must show that the patent claim "covers the alleged infringer's product or process." Markman v. Westview Instruments, Inc., 517 U.S. 370, 374 (1996). Thus, the initial step in an infringement analysis focuses on determining the meaning and scope of the claims of the patent. Wyeth v. Abbott Labs., No. 08-230, 2010 WL 3001913, at *1 (D.N.J. July 28, 2010) (citing Johnson Worldwide Assocs., Inc. v. Zebco Corp., 175 F.3d 985, 988 (Fed. Cir. 1995)). Notably, "[c]laim construction is a matter of law . . . therefore, it is '[t]he duty of the trial judge . . . to determine the meaning of the claims at issue.'" Id. (citing Exxon Chem. Patents, Inc. v. Lubrizoil Corp., 64 F.3d 1553, 1555 (Fed. Cir. 1995)).

In Phillips v. AWH Corp., the United States Court of Appeals for the Federal Circuit ("Federal Circuit") emphasized that "[i]t is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." 415 F.3d 1303, 1312 (Fed. Cir. 2005) (internal quotations omitted) (citing Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996) ("[W]e look to the words of the claims themselves . . . to define the scope of the patented invention.")) Generally, the words of a claim are given their "ordinary and customary meaning," which is defined as "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." Phillips, 415 F.3d at 1312-13 (citations omitted). In this regard, the Federal Circuit has noted the following:

> It is the person of ordinary skill in the field of the invention through whose eyes the claims are construed. Such person is deemed to read the words used in the patent documents with an understanding of their meaning in the field and to have knowledge of any special meaning and usage in the field. The inventor's words that are used to describe the invention-the inventor's lexicography-must be understood and interpreted by the court as they would be understood and interpreted by a person in that field of technology. Thus the court starts the decisionmaking process by reviewing the same resources as would that person, viz., the patent specification and the prosecution history.

Id. (quoting Multiform Desiccants, Inc. v. Medzam, Ltd., 133 F.3d 1473, 1477 (Fed. Cir. 1998)).

Importantly, in determining the meaning of a claim as understood by a person of ordinary skill in the art, the court may look to various sources from which the proper meaning may be discerned. Wyeth, 2010 WL 3001913, at *2. Specifically, "[t]hese sources include 'the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.'" Phillips, 415 F.3d at 1314 (citations omitted). "While a court is permitted to turn to extrinsic evidence, such evidence is generally of less significance and less value in the claim construction process. Extrinsic evidence would include evidence that is outside the patent and prosecution history, and may include expert testimony, dictionaries and treatises." Wyeth, 2010 WL 3001913, at *2. As courts have explained, "[s]uch evidence, though 'shed[ding] useful light on the relevant art,' is 'less significant than the intrinsic record in determining the legally operative meaning of claim language,' and 'is unlikely to result in a reliable interpretation of patent claim scope unless considered in context of the intrinsic evidence.'" Eppendorf AG v. Nanosphere, Inc., No. 09-0504, 2010 WL 2757097, at *2 (D. Del. July 12, 2010) (citing Phillips, 415 F.3d at 1317-19).

III. DISCUSSION

Term	Mylan's Proposed Construction	Ferring's Proposed Construction
Modified Release Material	A material that is known to and actually does modify the release of the active pharmaceutical ingredient in a tranexamic acid tablet formulation	A material that modifies the release of the active pharmaceutical ingredient

I find that the plain meaning of the phrase "modified release material" as used in the patent claims means "a material that modifies the release of the active pharmaceutical ingredient." This conclusion is based on the plain language of the '739 and '106 patent claims which indicate that the "modified release material" includes a polymer, such as, a hydroxyalkylcellulose or alkylcellulose, which modifies the release of the active pharmaceutical ingredient. ('739 patent at col. 69-72; '106 patent at col. 68-74.)

There is further support for this construction in the specifications that state "[i]n certain embodiments, the invention is further directed to a modified release oral dosage form comprising tranexamic acid or pharmaceutically acceptable salt thereof and a modified release material which provides for the modified release of the tranexamic acid or pharmaceutically salt thereof . . . ." ('739 patent at col. 7, ln. 48-53; '106 patent at col. 7, ln. 43-48; '795 patent at col. 3, ln. 10-15; '005 patent at col. 3, ln. 34-39.)

In further support of this construction, the specifications also state that "[t]o prepare modified release tablet formulations, the agent or modified release material to slow the release of tranexamic acid may be incorporated into the tablet matrix or coated onto the tablet surface or both." ('739 patent at col. 22, ln. 6-9; '106 patent at col. 22, ln. 4-7; '795 patent at col. 16, ln. 15-

18; '005 patent at col. 16, ln. 22-27; see also ('739 patent at col. 18, ln. 33-40); ('106 patent at col. 18, ln. 31-38; '795 patent at col. 12, ln. 40-47; '005 patent at col. 12, ln. 50-57.)

Ferring also submitted the declaration of Dr. Robert O. Williams, III, who also testified at the Markman hearing. Dr. Williams' conclusion is summed up in paragraph 26 of his declaration which states:

> In my opinion, the phrase "modified release material" as used in the claims of the patents-in-suit means a material that modifies the release of the active pharmaceutical ingredient. Indeed, the plain language of the claims indicates that the "modified release material" can include a polymer, such as, for example, a hydroxyalkylcellulose or alkylcellulose, which modifies the release of the active pharmaceutical ingredient. (*See, e.g.,* '739 patent at col. 69 line 45 - col. 72 line 26; '106 patent at col. 68 line 59 - col. 74 line 7; *see also* '005 patent at col. 36 line 52-54.)

(Ferring's Opening Claim Construction Br.; Ex. 10 (Williams' Decl.), ¶ 26.) After considering Dr. Williams' educational background and extensive experience in the field, I found his declaration and testimony to be persuasive.

Mylan's proposed construction would require us to change the construction of the same terms by a District Court in Nevada. The District Court in Nevada in considering the same claim terms of the '739 and '106 patents gave the phrase "modified release material" its plain and ordinary meaning and accepted Ferring's proffered construction of "a material that modifies the release of the active pharmaceutical ingredient." Ferring B.V. v. Watson Labs, Inc.-Fla., No. 11-0481, 2013 WL 499158, at *6-7 (D. Nev. Feb. 6, 2013).

On appeal, the Federal Circuit Court accepted this construction stating, "But under that construction, which we do not disturb, just because a certain material can modify release of the active pharmaceutical ingredient tranexamic acid, does not necessarily mean that it actually does."

Ferring B.V. v. Watson Labs, Inc.-Fla., 764 F.3d 1401, 1410 (Fed. Cir. 2014). Part of the language that Mylan asks us to add to the District Court's construction appears in the same sentence in which the Federal Circuit stated that they were not going to disturb the District Court's construction. If the Federal Circuit Court felt that the Federal District Court's construction needed to be changed, as suggested by Mylan, that was the perfect time to do it. The fact that the Circuit Court declined to make a change in the District Court's construction leads us to do likewise.

An appropriate Order follows.